III. REMARKS

The examiner acknowledges Applicant's election (with traverse) of Group I, claims 1-16, and the species 4-Fluoro-benzensulfonic acid 1-[trans-bis-(4-chloro- phenyl)-methyl]-2-methyl-azetidin-3-yl ester in the response filed 2/02/2006.

The examiner accepts applicant's traversal of the restriction requirement between Group I and claim 19 of Group III. Claim 19 and newly added claim 30 are hereby rejoined into Group I. As a result, claims 1-16, 19 and 30 are now part of Group I.

Status of the Claims

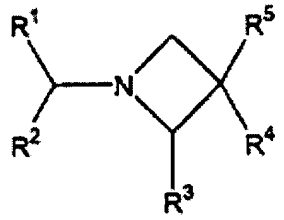
Claims 1-62 are currently pending in the instant application. Claims 31-62 are newly presented and represent the content originally present in claims 1-15 as preferred embodiments and which has been deleted from the previously existing claims to conform to standard formatting requirements. No new matter or new issues are presented. As the new claims represent the subject matter of previously elected claims they fall into the elected group and are presented for examination herein.

Claims 17, 18, and 20-29 are withdrawn from further consideration and claims 1-16, 19 & 30 (in part) are withdrawn from further consideration by the Examiner as being drawn to non-elected inventions under 37 CFR § 1.142(b).

Elected and Examined Subject Matter

The scope of the invention of the elected subject matter and the examined subject matter is as follows:

Compounds of the Formula I,



I

wherein:

$\mathbf{R^1}$ is as defined in claim 1;

$\mathbf{R^2}$ is as defined in claim 1;

$\mathbf{R^3}$ is a linear or branched, saturated or unsaturated, aliphatic group;

$\mathbf{R^4}$ is H, a cyano group, a carboxy group, or linear or branched alkyl group;

$\mathbf{R^5}$ is $O\text{-}SO_2\text{-}R^6$, $NHCO\text{-}R^7$, NH_2, or $NH\text{-}SO_2\text{-}R^8$;

$\mathbf{R^6}$ is linear or branched, saturated or unsaturated aliphatic group, a saturated or unsaturated cycloaliphatic group that does not contain a heteroatom;

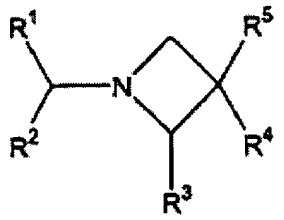
$\mathbf{R^7}$ is linear or branched, saturated or unsaturated aliphatic group, a saturated or unsaturated cycloaliphatic group that does not contain a heteroatom; and

$\mathbf{R^8}$ is linear or branched, saturated or unsaturated aliphatic group, a saturated or unsaturated cycloaliphatic group that does not contain a heteroatom.

Non-elected and Non-examined Subject Matter

The scope of the invention of the non-elected and non-examined subject matter is as follows:

Compounds of the Formula I



I

wherein:

R^3 is a cycloaliphatic group, which optionally contains a heteroatom, an optionally substituted aryl group, or a heteroaryl group;

R^4 is an optionally at least mono-substituted aryl group;

R^5 is NR^9-SO_2-R^{10} or O-CO-R^{11};

R^6 is a saturated or unsaturated cycloaliphatic group that contains a heteroatom, an optionally at least mono-substituted aryl group, or heteroaryl group;

R^7 is a saturated or unsaturated cycloaliphatic group that contains a heteroatom, an optionally at least mono-substituted aryl group, or heteroaryl group; and

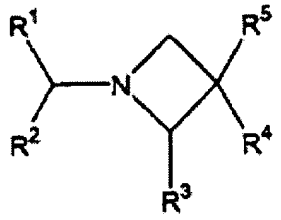
R^8 is a saturated or unsaturated cycloaliphatic group that contains a heteroatom, an optionally at least mono-substituted aryl group, or heteroaryl group.

Claim Rejections - 35 USC § 102

(1) Claims 1-6, 15, 19 & 30 stand rejected under 35 U.S.C. 102(b) as being anticipated by Frigola et al, "7-Azetidinylquinolones as Antibacterial Agents. 3. Synthesis, Properties and Structure-

Activity Relationships of the Stereoisomers Containing a 7-(3-Amino-2-methyl-1-azetidinyl) Moiety," J. Med. Chem. 38(7) 1203-15 (1995).

As amended, claims 1-6 and 15 of the instant application are, in part, drawn to a compound of formula I



I

wherein R^1 is substituted phenyl; R^2 is phenyl; R^3 is an aliphatic group; R^4 is H; and R^5 is an NH_2 moiety.

Claims 19 and 30 are drawn to a medicament comprising a compound of formula (I) and a pharmaceutically acceptable carrier.

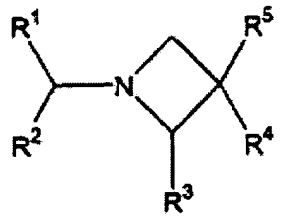
At p. 1205, Table 1, Frigola et al. disclose certain compounds identified as 18a-d. All of Frigola et al.'s compounds show unsubstituted phenyl groups as substituent R^1

As amended, the present claims relate to compounds where R^1 represents only substituted phenyl. Thus, formula I of the presently claimed invention no longer encompasses the example compounds of Frigola et al. (Journal of Medicinal Chemistry, 1995, 38, 1203-1215 and Journal of Medicinal Chemistry, 1994, 37, 4195-4210), because the reference compounds possess only unsubstituted phenyl groups as the substituent R^1.

Applicant respectfully submits that this amendment obviates this ground for rejection.

(2) Claims 1-6, 15, 19 & 30 stand rejected under 35 U.S.C. 102(b) as being anticipated by Frigola et al., "7-Azetidinylquinolones as Antibacterial Agents. 2. Synthesis and Biological Activity of 7-(2,3-Disubstituted-1-azetidinyl)-4-oxoquinolineand -1,8-naphthyridine-3-carboxylic Acids. Properties and Structure-Activity Relationships of Quinolones with an Azetidine Moiety," J. Med. Chem., 37(24), pp. 4195-210 (1994).

As amended, claims 1-6 and 15 of the instant application are, in part, drawn to a compound of formula



I

wherein R^1 is substituted phenyl; R^2 is phenyl; R^3 is an aliphatic group; R^4 is H; and R^5 is an NH_2 moiety.

Claims 19 and 30 are drawn to a medicament comprising a compound of formula (I) and a pharmaceutically acceptable carrier.

Frigola et al. disclose certain compounds at p. 4196, Table 1, compounds 18f, 18g, 18h, and 18j). All of Frigola et al.'s compounds show unsubstituted phenyl groups as substituent R^1.

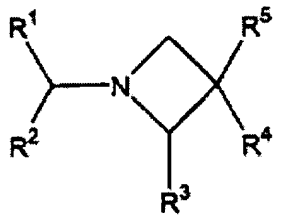
As amended, the present claims now relate to compounds where R^1 represents only substituted phenyl. Thus, formula 1 of the presently claimed invention no longer encompasses the compounds of Frigola et al. (Journal of Medicinal Chemistry, 1995, 38, 1203-1215 and Journal

of Medicinal Chemistry, 1994, 37, 4195-4210), because the reference compounds possess unsubstituted phenyl groups as substituent R^1.

Applicant respectfully submits that this amendment obviates this ground for rejection.

(3) Claims 1-6 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Pinol et al., US 5,073,646.

As amended, claims 1-6 and 15 of the instant application are drawn, in part, to a compound of formula



I

wherein R^1 is substituted phenyl; R^2 is phenyl; R^3 is an aliphatic group; R^4 is H or an alkyl group; R^5 is an NH_2 moiety, or an O-SO_2-R^6-moiety; and R^6 is an aliphatic group.

Pinol et al. disclose certain compounds having an unsubstituted phenyl moiety at R^1.

As amended, Formula 1 of the presently claimed invention is not inclusive of the compounds of Pinol et al. because the compounds and the formula disclosed in he Pinol et al. require a diphenylmethyl moiety which is totally unsubstituted on the azetidinyl ring whereas the compounds of the presently claimed invention have to be at least mono-substituted at the diphenyimethyl moiety.

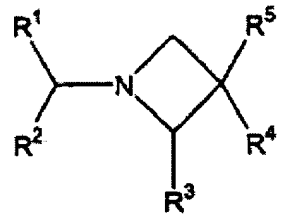
Applicant respectfully submits that this amendment obviates this

ground for rejection.

Claim Rejections - 35 USC § 103

Claims 1-6, 15, 19 and 30 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Frigola et al., "7-Azetidinylquinolones as Antibacterial Agents. 2. Synthesis and Biological Activity of 7-(2,3-Disubstituted-1-azetidinyl)-4-oxoquinoline and -1,8-naphthyridine-3-carboxylic Acids. Properties and Structure-Activity Relationships of Quinolones with an Azetidine Moiety," J. Med. Chem., 37(24), pp. 4195-210 (1994).

As amended, claims 1-6, 9 and 15 of the instant application are, in part, drawn to a compound of formula (I),



I

wherein R^1 is substituted phenyl; R^2 is phenyl; R^3 is an aliphatic group; R4 is H; R^5 is an NH_2 moiety, or an $NH\text{-}SO_2\text{-}R^8$ moiety; R^8 is an optionally substituted 6-membered aryl group; with the exclusion of compounds wherein R^1 and R^2 are each unsubstituted phenyl, R^5 is $O\text{-}SO_2\text{-}R^6$ and R^6 is methyl.

Claims 19 and 30 are drawn to a medicament comprising a compound of formula (I) and a pharmaceutically acceptable carrier.

The examiner acknowledges that Frigola et al. disclose compounds which contain two methyl groups bonded in to the

azetidine ring in the 2-position while applicant's compounds contain only one methyl group. As amended, applicant's claims also differ from those of the cited art in the applicant's R^1 substituent is substituted phenyl while the R^1 substituent of Frigola et al. is limited to unsubstituted phenyl.

Furthermore, Frigola et al. does not disclose any antibacterial activity or pharmacokinetic properties of the inventively claimed azetidinyl compounds.

Frigola et al. disclose antibacterial activity solely for quinolonyl and naphthyridinyl compounds with azetidinyl compounds as substituents in position 7 of the quinolonyl ring (page 4196, column 1 and abstract). Azetidinyl compounds with a diphenylmethyl moiety were only prepared for synthetic reasons and for reasons of stereochemical assignment. Consequently, antibacterial activity is not disclosed for the inventively claimed azetidinyl compounds.

Thus, it is both unexpected and surprising that the inventively claimed compounds of general formula I are pharmacologically active at all.

In particular, there is no hint in Frigola et al. that the azetidinyl compounds described therein show any affinity for cannabinoid receptors and, accordingly, could be used in the treatment of diseases that are modulated by the inventively claimed azetidinyl compounds of formula I. there is no disclosure that the presently claimed compounds are pharmacologically active at all and in particular, no disclosure that they could be useful in the treatment of diseases that are modulated by cannabinoid receptors.

In addition, the reference of Frigola at al. discloses azetidinyl compounds that also differ from the compounds of the presently claimed invention structurally in the kind of substitution of the diphenylmethyl moiety on the azetidinyl ring and optionally in the degree of substitution in the 2-position of the azetidinyl ring.

As Frigola et al. does not disclose how or if at all a diphenylmethyl moiety on an azetidinyl ring can be modified to obtain compounds that show any pharmacological activity it is both unexpected and surprising that the inventively claimed compounds of general formula I show any pharmacological activity at all.

Applicant respectfully requests reconsideration of this ground for rejection.

Claim Objections

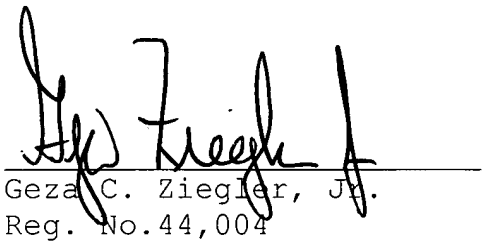
Claims 1-16, 19 and 30 are objected to as being drawn to non-elected subject matter.

These claims have been amended to remove the non-elected subject matter thus obviating this ground for objection.

Conclusion

The foregoing amendments are believed to place the application in condition for allowance. Applicant requests favorable reconsideration of the claims. A check for $1,500.00 is enclosed for the new claims. The Commissioner is hereby authorized to charge payment for any other fees associated with this communication or credit any over payment to Deposit Account No. 16-1350.

Respectfully submitted,



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2 June 2006
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